

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA  
Civ. No. 13-3003 (WMW/DTS)

United States of America,  
*ex rel.* Kipp Fesenmaier,

Plaintiffs,

v.

The Cameron-Ehlen Group, Inc.,  
d/b/a Precision Lens, and Paul Ehlen,

Defendants.

**JOINT PROPOSED  
JURY INSTRUCTIONS**

Pursuant to the Court's July 20, 2022 Order, ECF No. 737, the parties jointly submit the attached Proposed Jury Instructions and Draft Verdict Forms. The parties reserve their respective rights to supplement or amend these proposed instructions based on the evidence introduced at trial.

Dated: November 23, 2022

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**Preliminary Instruction No. 1  
Before Voir Dire**

Members of the Jury Panel, we are about to begin the process of selecting which of you will be the jury that tries this case. In that process you will be asked questions by me or by the attorneys or by both that touch on your qualifications to sit as jurors in this case. You will be placed under oath or asked to affirm that you will truthfully and completely answer these questions put to you.

Your undivided attention to this process is very important. So, if you have a cell phone or other communication device, please take it out now and turn it off. Do not turn it to vibration or silent; please power it down or off. During this jury selection process, you must leave it off.

During this jury selection process and during the trial, it is important that all the information you receive about the case comes from the courtroom. So, from now on until you are discharged from the case you may not discuss this case with anyone (and that includes the other potential jurors) except during deliberations if you are selected as a juror. However, you may tell your family, close friends, and other people about your participation in this trial, but only so they will know when you are required to be in court. If you do that, please warn them not to ask you about this case or try to tell you anything they know or think they know about it, or discuss this case in your presence.

Also, just as importantly, you must not communicate any information at all about the case to anyone by any means, directly or indirectly, in face-to-face conversation or by any digital or social media. It's not enough to just not name the case or the people

involved—you must refrain from all conversations or discussion (online or in-person) about the case, including any hints or veiled references.

If you discuss the case with someone other than the other jurors during deliberations, you may be influenced in your verdict by the opinions of people other than the other jurors. That would not be fair to the parties and it would result in a verdict that is not based entirely on the evidence in court and the law the court gives you.

It is very important that you abide by these rules. Failure to follow these instructions, and indeed any instructions the court gives you during the trial could result in the case having to be retried. And failure to follow these and the court's other instructions could result in you being held in contempt of court and punished accordingly.

Those of you who are selected to try this case will receive similar instructions as we go through the trial.

Are there any of you who cannot or will not abide by these rules concerning communication with others during this trial?

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.01 (2021).

**Preliminary Instruction No. 2**  
**Outline of Trial**

The trial will proceed in the following manner:

First, the lawyer for the United States will make an opening statement. Next, the defendants' lawyers may make an opening statement. An opening statement is not evidence, but it is a summary of the evidence the lawyers expect you will see and hear during the trial.

After opening statements, counsel for the United States, with the assistance of counsel for Relator, will then present evidence. The defendants' lawyers will have a chance to cross-examine the United States' witnesses. After the United States has finished presenting its case, the defendants may present evidence, and the United States' lawyers, with the assistance of counsel for Relator, will have a chance to cross-examine their witnesses. In order to make this process as efficient as possible, the defendants may present some of their evidence during the United States' presentation of its case. The United States' lawyers will have a chance to cross-examine the defendants' witnesses whenever they are called by the defendants.

After you have seen and heard all of the evidence from both sides, the lawyers will make closing arguments that summarize and interpret the evidence. Just as with opening statements, closing arguments are not evidence. [Before] [After] the closing arguments, I will instruct you further on the law. After the lawyers' arguments and after the court's instructions you will go to the jury room to deliberate and decide on your verdict.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.09 (2021).



**Preliminary Instruction No. 3**  
**Recess at End of Voir Dire**

During this recess, and every other recess, do not discuss this case among yourselves or with anyone else, including your family and friends. Do not allow anyone to discuss the case with you or within your hearing. “Do not discuss” also means do not e-mail, send text messages, post on any form of social media, blog or engage in any other form of written, oral or electronic communication, as I instructed you earlier.

You must decide this case only from the evidence received by the court here in the courtroom and the instructions on the law that I give you.

Do not read any newspaper or other written account online or otherwise, watch any televised account or streamed video account, or listen to any streamed internet or radio program on the subject of this trial.

Do not conduct any Internet research or consult with any other sources about this case, the people involved in the case, its general subject matter, or the law.

You must keep your mind open and free of outside information. Only in this way will you be able to decide the case fairly, based solely on the evidence received in court and my instructions on the law. If you decide this case on anything else, you will have done an injustice. It is very important that you follow these instructions.

I might not repeat these things to you before every recess, but keep them in mind until you are discharged.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.02 (2021).

**Preliminary Instruction No. 4**  
**General; Nature of Case; Duty of Jury; Cautionary**

Members of the Jury: Now that you have been sworn, I am going to give you some instructions about this case and about your duties as jurors. At the end of the trial I will give you more instructions. I may also give you instructions during the trial. All instructions - those I give you now and those I give you later - whether they are in writing or given to you orally – are equally important and you must follow them all.

You must leave your cell phone, tablet computer, and any other electronic devices in the jury room during the trial and may only use them during breaks. However, you are not allowed to have those devices in the jury room during your deliberations. You must give them to the [bailiff] [deputy clerk] [court security officer] for safekeeping just before you start to deliberate. They will be returned to you when your deliberations are complete.

This is a civil case brought by the United States of America under a law called the False Claims Act, which is a federal law designed to discourage fraud against the federal government. The False Claims Act authorizes the United States to recover damages for false or fraudulent claims for payment submitted to the United States. In this case, the Government seeks relief under the False Claims Act for the defendants' alleged violations of the Anti-Kickback Statute.

There are two defendants in this case. One defendant is The Cameron-Ehlen Group, Inc., which does business and will be referred to throughout this trial as Precision Lens. Precision Lens is a company that distributes intraocular lenses (called IOLs) that are implanted by ophthalmologists to correct various eye problems (like cataracts), as well as

other surgical supplies used during those surgeries. Precision Lens is owned and, during the time relevant to this case, was run by Paul Ehlen, who is the other defendant here.

The False Claims Act allows a private citizen, called the “Relator,” to bring an action on behalf of the United States against a company or individual alleged to have violated the False Claims Act. Here, Kipp Fesenmaier is the relator. After a case is filed by a relator, the United States has the opportunity to investigate the allegations. If it so chooses, the United States may take over the case and assume the primary responsibility for prosecuting it. The United States has done so in this case, and while the relator is still a party, the United States is the party primarily responsible for litigating this case.

In this case, the United States of America alleges that, between January 1, 2006 and December 31, 2015 the defendants violated the False Claims Act by offering and providing illegal kickbacks to certain ophthalmologists who performed surgeries paid for by Medicare using products distributed by the defendants.

Medicare is a federal healthcare program that pays doctors and others for healthcare services that they provide to beneficiaries. The Anti-Kickback Statute, or AKS, is part of the Social Security Act, which governs federally funded healthcare programs such as Medicare. The purpose of the AKS is to protect the Medicare program from increased costs and abusive practices resulting from healthcare provider decisions that are based on financial self-interest rather than the quality and necessity of the services and items being provided, and also to protect patients from doctors whose medical judgments might be clouded by improper financial considerations.

The Anti-Kickback Statute prohibits individuals or entities from knowingly and willfully asking for offering or paying anything of value (called “remuneration”) in return for purchasing or ordering, or recommending the purchasing or ordering of, any item that is paid for by Medicare.

**[Plaintiffs’ Proposed Language: *The Anti-Kickback statute is violated if at least one purpose of the remuneration is to induce the purchasing, ordering, arranging, or recommending of an item.*]**

**[Defendants’ Proposed Language: *The Anti-Kickback statute is violated if the primary purpose of the remuneration is to induce the purchasing, ordering, arranging, or recommending of an item.*]**

The United States alleges that the defendants offered and provided remuneration to certain ophthalmologists in the form of kickbacks, such as hunting and skiing trips, dinners and other social engagements or sporting events, private flights, and the use of frequent-flyer miles to purchase below-market airline tickets, in exchange for those ophthalmologists’ use or continued use of products distributed by the defendants.

It will be your duty to decide from the evidence whether the United States is entitled to a verdict against the defendants. You and only you will be the judges of the facts. I play no part in deciding whether a fact was more likely to have happened or not. You should not take anything I may say or do during the trial as indicating what I think of the evidence or what your verdict should be. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal

principles that must guide you in your decisions. You must follow the law I present to you whether you agree with it or not.

The Defendants contend that they did not provide any physicians with any illegal kickbacks.

Defendants also content that they sought legal advice regarding social activities and how to remain compliant with the law.

Your duty is to decide what the facts are from the evidence.

You are allowed to consider the evidence in the light of your own observations and experiences. After you have decided what the facts are, you will have to apply those facts to the law that I give you in my instructions. That is how you will reach your verdict. You must follow my instructions, whether you agree with them or not. You have taken an oath to follow the law that I give you in my instructions. The law requires you to come to a just verdict based only on the evidence, your common sense, and the law that I give you in my instructions, and nothing else.

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe all of what a witness said, or only part of it, or none of it. You may, for example, consider a witness's opportunity to see, hear, or know the things testified about; a witness's memory; any reasons a witness might have for testifying a certain way; how a witness acted while testifying; the reasonableness of a witness's testimony in light of all the evidence; and whether or to what extent a witness's testimony is consistent with or contradicted by other evidence you believe. Do not let sympathy, or your own likes or dislikes, influence you. The law requires you to

come to a just verdict based only on the evidence, your common sense, and the law that I give you in my instructions, and nothing else.

**Plaintiffs' Source(s):** 8TH CIR. CIVIL JURY INSTR. § 1.03, § 3.03 (2021), modified.

**Defendants' Source(s):** 8TH CIR. CIVIL JURY INSTR. § 1.03, § 3.03 (2021), modified.

### **Plaintiffs' Statement in Support of Their Position**

Plaintiffs' proposed language regarding the "one purpose" standard accurately reflects this Court's order on the parties' cross motions for summary judgment. *See* ECF No. 722 at 17. Following the overwhelming weight of authority, this Court adopted the "one purpose" standard, holding "the weight of persuasive authority reflects that Plaintiffs need only prove that *one* of the purposes of the remuneration Defendants offered or paid was to induce Medicare purchases." *Id.* Defendants did not expressly dispute the applicability of the "one purpose" standard at summary judgment, *see id.*, and should not be permitted to now raise objections on the eve of trial by contesting Plaintiffs' proposed jury instruction on this settled issue.

As this Court recognized, every appellate court to address this issue in the context of a civil FCA case premised on AKS violations has held that an AKS violation exists if *one* purpose of the remuneration was to induce Medicare purchases, even if other legitimate purposes for the remuneration existed. *See, e.g., United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (collecting cases from the Third, Fifth, Ninth, and Tenth Circuits). In *Borrasi*, the Seventh Circuit rejected the defendant's argument that inducement must be "the primary motivation behind the remuneration" because nothing in the text of the AKS supports such a requirement. ECF No. 722 at 17, citing 639 F.3d at 781-82. "Each circuit to actually reach the issue has rejected the primary motivation theory [defendant] advocates." *Borrasi*, 639 F.3d at 782. Since this Court's summary judgment decision, the Fourth Circuit has joined this list. *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021). Defendants invoke the "primary purpose" standard based on the Eighth Circuit Model Instructions for criminal AKS cases, but "the Model Instructions are 'merely helpful suggestions to assist the district courts.'" *United States ex rel. Cairns v. D.S. Med., LLC*, No. 1:12CV00004 AGF, 2017 U.S. Dist. LEXIS 140628, at \*11-12 (E.D. Mo. Aug. 31, 2017) quoting *United States v. Norton*, 846 F.2d 521, 525 (8th Cir. 1988).

Plaintiffs' other proposed language is drawn from the Eighth Circuit model instructions cited and provides background and context that will assist the jury in understanding their role and the Court's role.

### **Defendants' Statement in Support of Their Position**

Defendants' proposed instruction on remuneration tracks the Eighth Circuit's Model Criminal Jury Instructions and recognizes that for Anti-Kickback Statute liability to attach, the intent to induce must be the "primary purpose" of the remuneration. *See* Model Instruction 6.42.1320: Soliciting or Receiving Kickbacks in Connection with Medicare or Federal Health Care Program Payments (42 U.S.C. § 1320A7B(B)(1)(A)) ("...the [remuneration] was [solicited or paid] **primarily in order to** [induce] [and] [or] [in exchange for] the referral of a patient insured by" a federal health care program); *see also* *U.S. v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) (government must meet "heightened mens rea burden" because AKS potentially includes conduct that is not "obviously nefarious"); *id.* at 442 ("The essence of a scheme to defraud is an intent to harm the victim. When there has been no actual harm, 'the government must produce evidence independent of the alleged scheme to show the defendant's fraudulent intent.'"). Even if the Court determines that the Eighth Circuit model instruction is not definitive, the rule of lenity further counsels in favor of an instruction more favorable to defendants. *U.S. v. Santos*, 553 U.S. 507, 514 (2008) ("The rule of lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them."); *U.S. v. Cooper*, 48 F.4th 428, 434 (5th Cir. 2022) (applying rule of lenity is construing Anti-Kickback Statute).

Defendants oppose the use of the word "expensive" in connection with the conduct at issue because it is a subjective adjective irrelevant to the issues to be tried. Such language is irrelevant, provides no probative value, and will unduly prejudice the jury against Defendants by essentially putting Defendants on trial for being wealthy, in violation of Federal Rules of Evidence 401, 402, and 403. Defendants' position on the use of irrelevant and prejudicial subjective modifiers is further discussed and supported in its Motion in Limine at ECF 742.

Plaintiffs propose additional, unnecessary prefatory language that is not in the model instruction and substantially lengthens the instruction; this approach is repetitive and unnecessarily confusing. Defendants propose a simple statement summarizing the core issues to keep the jurors' attention focused on the task at hand. To the same end, Defendants propose language reminding the jury to make its decision based on the law rather than emotions. Defendants elaborate on the concern that Plaintiffs seek to exploit emotional juror response in its Motion in Limine at ECF 746.



**Preliminary Instruction No. 5**  
**Evidence; Limitations**

When I use the word “evidence,” I mean the testimony of witnesses, documents and other things I receive as exhibits, facts that I tell you the parties have agreed are true, and any other facts that I tell you to accept as true.

Some things are not evidence. I will tell you now what is not evidence:

1. Lawyers’ statements, arguments, questions, and comments are not evidence.
2. Documents or other things that might be in court or talked about, but that I do not receive as exhibits are not evidence.
3. Objections are not evidence. Lawyers have a right – and sometimes a duty – to object when they believe something should not be a part of the trial. Do not be influenced one way or the other by objections.

If I sustain a lawyer’s objection to a question or an exhibit, that means the law does not allow you to consider that information. When that happens, you have to ignore the question or the exhibit, and you must not try to guess what the information might have been.

4. Testimony and exhibits that I strike from the record, or tell you to disregard, are not evidence, and you must not consider them.
5. Anything you see or hear about this case outside the courtroom is not evidence, and you must not consider it.

Also, I might tell you that you can consider a piece of evidence for one purpose only, and not for any other purpose. If that happens, I will tell you what purpose you can

consider the evidence for and what you are not allowed to consider it for. You need to pay close attention when I give an instruction about evidence that you can consider for only certain purposes, because you might not have that instruction in writing later in the jury room.

Some of you may have heard the terms “direct evidence” and “circumstantial evidence.” **[Plaintiffs’ Proposed Language: *For example, if a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining. Another form of direct evidence is an exhibit where the fact to be proved is its existence or current condition. “Circumstantial evidence” is proof of one or more facts from which you could find another fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.***

***You should consider both kinds of evidence that are presented to you. The law makes no distinction between the weight to be given to direct and circumstantial evidence. Your role is to decide how much weight to give any evidence.]***

**[Defendants’ Proposed Language: *Some of you may have heard the terms “direct evidence” and “circumstantial evidence.” You should not be concerned with those terms, since the law makes no distinction between the weight to be given to direct and circumstantial evidence.***

**Plaintiffs’ Source(s):** 8TH CIR. CIVIL JURY INSTR. § 1.04 (2021), modified.

**Defendants’ Source(s):** 8TH CIR. CIVIL JURY INSTR. § 1.04 (2021).

**Plaintiffs' Statement in Support of Their Position**

Plaintiffs propose a reasonable explanation of direct and circumstantial evidence that will assist the jury in understanding the types of evidence it will consider. Defendants' proposed language is confusing. The jury should not be instructed that it should not be concerned with the terms "direct evidence" and "circumstantial evidence" because circumstantial evidence may inform the jury's assessment of Defendants' intent. *See* Pltfs' Proposed Closing Instruction 35P. Informing the jury of this distinction at the outset of the case provides necessary context and ensures the instructions are tailored to the law applicable to this case.

**Defendants' Statement in Support of Their Position**

Defendants' proposed instruction directly tracks Eighth Circuit Model Civil Jury Instruction 1.04. Plaintiffs' gloss places an unnecessary burden on the jurors to consider and weigh direct and circumstantial evidence when—as the model instruction makes clear—they are neither required nor expected to do so. Plaintiffs' proposed instruction risks confusing the jury concerning their responsibility.

**Preliminary Instruction No. 6**  
**Bench Conferences and Recesses**

During the trial, I will sometimes need to talk privately with the lawyers. I may talk with them here at the bench while you are in the courtroom, or I may call a recess and let you leave the courtroom while I talk with the lawyers. Either way, please understand that while you are waiting, we are working. We have these conferences to make sure that the trial is proceeding according to the law and to avoid confusion or mistakes. We will do what we can to limit the number of these conferences and to keep them as short as possible.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.05 (2021).

**Preliminary Instruction No. 7**  
**No Transcript Available [Note-Taking]**

At the end of the trial, you will have to make your decision based on what you recall of the evidence. You will not have a written copy of the testimony to refer to. Because of this, you must pay close attention to the testimony and other evidence as it is presented here in the courtroom.

[If you wish, however, you may take notes to help you remember what the witnesses say. If you take notes, do not show them to anyone until you and your fellow jurors go to the jury room to decide the case after you have heard and seen all of the evidence. And do not let taking notes distract you from paying close attention to the evidence as it is presented. The Clerk will provide each of you with a pad of paper and a pen or pencil. At each recess, leave them \_\_\_\_\_.]

[When you leave at night, your notes will be locked up and returned to you when you return. When the trial is over your notes will be destroyed. They will not be read by anyone other than you.]

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.06 (2021).

**Preliminary Instruction No. 8**  
**Questions by Jurors**

When the lawyers have finished asking all of their questions of a witness, you will be allowed to ask the witness questions (describe procedure to be used here). I will tell you if the rules of evidence do not allow a particular question to be asked. After all of your questions, if there are any, the lawyers may ask more questions. [Do not be concerned or embarrassed if your question is not asked; sometimes even the lawyers' questions are not allowed.]

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.07 (2021).

**Preliminary Instruction No. 9**  
**Conduct of the Jury**

Jurors, to make sure this trial is fair to the parties, you must follow these rules:

*First*, do not talk or communicate among yourselves about this case, or about anyone involved with it, until the end of the trial when you go to the jury room to consider your verdict.

*Second*, do not talk with anyone else about this case, or about anyone involved with it, until the trial has ended and you have been discharged as jurors.

*Third*, when you are outside the courtroom, do not let anyone tell you anything about the case, or about anyone involved with it until the trial has ended and your verdict has been accepted by me. If someone tries to talk to you about the case during the trial, please report it to the [bailiff] [deputy clerk].

*Fourth*, during the trial, do not talk with or speak to any of the parties, lawyers, or witnesses in this case – not even to pass the time of day. It is important not only that you do justice in this case, but also that you act accordingly. If a person from one side of the lawsuit sees you talking to a person from the other side – even if it is just about the weather – that might raise a suspicion about your fairness. So, when the lawyers, parties and witnesses do not speak to you in the halls, on the elevator or the like, please understand that they are not being rude. They know they are not supposed to talk to you while the trial is going on, and they are just following the rules.

*Fifth*, you may need to tell your family, close friends, and other people that you are a part of this trial. You can tell them when you have to be in court. But you must warn them



not to ask you about this case, tell you anything they know or think they know about this case, or talk about this case in front of you. Remember: You must not communicate with anyone in any manner about anything or anyone, including the court, related to this case.

You must not tell anyone anything about the jury's deliberations in this case until after I accept your verdict or until I give you specific permission to do so. If you talk about the case with someone besides the other jurors during deliberations, it looks as if you might already have decided the case or that you might be influenced in your verdict by their opinions. That would not be fair to the parties, and it might result in the verdict being thrown out and the case having to be tried over again.

During the trial, while you are in the courthouse and after you leave for the day, do not give any information to anyone, by any means, about this case.

*Sixth*, do not do any research or investigate the case facts or the law-- on the Internet, in libraries, newspapers, dictionaries, by talking to anyone, or otherwise. Do not visit or view any place discussed in this case, and do not use the Internet or other means to search for or view any place discussed in the testimony.

*Seventh*, do not read or otherwise receive any information, including any news stories or Internet articles or blogs that are about the case, or about anyone involved with it. Do not listen to any radio or television reports, or digital streaming, about the case or about anyone involved with it. In fact, until the trial is over I suggest that you avoid at all reading or receiving any digital streaming or any newspapers or news journals, avoid viewing social media, and avoid listening to any television or radio newscasts at all. I do not know whether there will be news reports about this case, but if there are, you might

accidentally find yourself reading or listening to something about the case. If you want, you can have someone collect information or clip out any stories and set them aside to give to you after the trial is over. I assure you, that by the time you have heard all the evidence in this case, you will know what you need to return a just verdict.

The parties have a right to have you decide their case based only on evidence admitted here in court. If you research, investigate, or experiment on your own, or get information from other sources, your verdict might be influenced by inaccurate, incomplete, or misleading information. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through cross-examination. All of the parties are entitled to a fair trial before an impartial jury, and you have to conduct yourselves in a way that assures the integrity of the trial process. If you decide a case based on information not admitted in court, you will deny the parties a fair trial. You will deny them justice. Remember, you have taken an oath to follow the rules, and you must do so; if you do not, the case might have to be retried, and you could be held in contempt of court and possibly punished.

*Eighth*, do not make up your mind during the trial about what your verdict should be. Keep an open mind until after you and your fellow jurors have discussed all the evidence.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 1.08 (2021).

**Trial Instruction No. 10**  
**Duties of Jury; Recesses**

During this recess, and every other recess, do not discuss this case among yourselves or with anyone else, including your family and friends. Do not allow anyone to discuss the case with you or within your hearing. “Do not discuss” also means do not e-mail, send text or direct messages, post or comment on social media, blog or engage in any other form of written, oral or electronic communication, as I instructed you before.

Do not read or listen to any statements about this trial in any method of communication, including any newspaper or other written account, any televised account, any radio program, any social media or digital streaming or other production, on the Internet or elsewhere. Do not conduct any Internet research or consult with any other sources about this case, the people involved in the case, or its general subject matter. You must keep your mind open and free of outside information. Only in this way will you be able to decide the case fairly based solely on the evidence and my instructions on the law. If you decide this case on anything else, you will have done an injustice. It is very important that you follow these instructions.

I may not repeat these things to you before every recess, but keep them in mind throughout the trial.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.01 (2021).

**Trial Instruction No. 11**  
**Stipulated Testimony**

The plaintiff[s] and the defendant[s] have stipulated - that is, they have agreed - that if \_\_\_\_\_ were called as a witness [(he) (she)] would testify in the way counsel have just stated. You should accept that as being \_\_\_\_\_'s testimony, just as if it had been given here in court from the witness stand.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.02 (2021).

**Trial Instruction No. 12**  
**Stipulated Facts**

The parties have stipulated – that is, they have agreed – that certain facts are as counsel have just stated. You must, therefore, treat those facts as having been proved.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.03 (2021).

**Trial Instruction No. 13**  
**Judicial Notice**

I have decided to accept as proved the following fact[s]: \_\_\_\_\_.

You must accept [(this) (these)] fact[s] as proved.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.04 (2021).

**Trial Instruction No. 14**  
**Transcript of Recorded Conversation**

As you have heard, there is a typewritten transcript of the [audio] [video] recording [I just mentioned] [you are about to hear] [you are about to see]. That transcript also undertakes to identify the speakers engaged in the conversation.

You are permitted to have the transcript for the limited purpose of helping you follow the conversation as you listen to the recording, and also to help you identify the speakers. The recording is evidence for you to consider. The transcript, however, is not evidence.

You are specifically instructed that whether the transcript correctly or incorrectly reflects the conversation or the identity of the speakers is entirely for you to decide based upon what you have heard here about the preparation of the transcript, and upon your own examination of the transcript in relation to what you hear on the recording. The recording itself is the primary evidence of its own contents. If you decide that the transcript is in any respect incorrect or unreliable, you should disregard it to that extent.

Differences between what you hear in the recording and read in the transcript may be caused by such things as the inflection in a speaker's voice, or by inaccuracies in the transcript. You should, therefore, rely on what you hear rather than what you read when there is a difference.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.05 (2021).

**Trial Instruction No. 15**  
**Evidence Admitted for Limited Purpose**

The evidence [(you are about to hear) (you have just heard)] may be considered by you only on the [(issue) (question)] of \_\_\_\_\_. It may not be considered for any other purpose.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.09 (2021).



**Trial Instruction No. 16**  
**Demonstrative Summaries Not Received as Evidence**

Certain charts and summaries have been shown to you in order to help explain the facts disclosed by the books, records, or other underlying evidence in the case. Those charts or summaries are used for convenience. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and decide the facts from the books, records or other underlying evidence.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.11 (2021).

**Trial Instruction No. 17**  
**FRE Rule 1006 Summaries**

Certain [schedules] [summaries] [charts] were admitted in evidence [as Exhibits \_\_ and \_\_]. You may use those [schedules] [summaries] [charts] as evidence, even though the underlying documents and records are not here. [However, the [accuracy] [authenticity] of those [schedules] [summaries] [charts] has been challenged. It is for you to decide how much weight, if any, you will give to them. In making that decision, you should consider all of the testimony you heard about the way they were prepared.]

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.12 (2021).

**Trial Instruction No. 18**  
**Deposition Evidence at Trial**

Testimony will now be presented to you in the form of a deposition. A deposition is the recorded answers a witness made under oath to questions asked by lawyers before trial. The deposition testimony to be offered will come in two forms: Some was recorded in writing and will be read to you; other testimony was electronically video recorded and that recording will be played for you. You should consider the deposition testimony, and judge its credibility, as you would that of any witness who testifies here in person. When the deposition is read to you, you should not place any significance on the manner or tone of voice used to read the witness's answers to you.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 2.14 (2021).

**Closing Instruction No. 19**  
**Additional Instructions**

Members of the jury, the instructions I gave at the beginning of the trial and during the trial are still in effect. Now I am going to give you additional instructions.

You have to follow all of my instructions – the ones I gave you earlier, as well as those I give you now. Do not single out some instructions and ignore others, because they are all important. This is true even though I am not going to repeat some of the instructions I have already given you.

[You will have copies of [the instructions I am about to give you now] [all of the instructions] in the jury room. [You will have copies of some of the instructions with you in the jury room; others you will not have copies of. This does not mean some instructions are more important than others.] Remember, you have to follow all instructions, no matter when I give them, whether or not you have written copies.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 3.01 (2021).

**Closing Instruction No. 20**  
**Judge's Opinion**

I have not intended to suggest what I think your verdict[s] should be by any of my rulings or comments during the trial.

[During this trial I have asked some questions of witnesses. Do not try to guess my opinion about any issues in the case based on the questions I asked.]

**Source:** 8TH CIR. CIVIL JURY INSTR. § 3.02 (2021).

**Closing Instruction No. 21**  
**Credibility of Witnesses**

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe all of what a witness said, or only part of it, or none of it.

You may consider a witness's intelligence; the opportunity the witness had to see or hear the things testified about; a witness's memory, knowledge, education, and experience; any reasons a witness might have for testifying a certain way; how a witness acted while testifying; whether a witness said something different at another time; whether a witness's testimony sounded reasonable; and whether or to what extent a witness's testimony is consistent with other evidence you believe.

In deciding whether to believe a witness, remember that people sometimes hear or see things differently and sometimes forget things. You will have to decide whether a contradiction is an innocent misrecollection, or a lapse of memory, or an intentional falsehood. That may depend on whether it has to do with an important fact or only a small detail.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 3.03 (2021).

**Closing Instruction No. 22**  
**Burden of Proof**

*[Plaintiffs' Proposed Language: You must decide whether certain facts have been proved by what the law calls a "preponderance" or the greater weight of the evidence. This means that you must decide whether the United States had proved, in light of all the evidence, that what it claims happened is more likely true than not. So, if you could put the evidence favoring the United States and the evidence favoring the defendants on opposite sides of balancing scales, the United States needs to make the scales tip to its side. If the United States fails to meet this burden, you must find in favor of the defendants.]*

*[Defendants' Proposed Language: You must decide whether certain facts have been proved by the greater weight of the evidence. A fact has been proved by the greater weight of the evidence, if you find that it is more likely true than not true. You decide that by considering all of the evidence and deciding what evidence is more believable.]*

On certain issues, called "affirmative defenses," the defendants Precision Lens and Paul Ehlen have the burden of proof. That means they must prove the elements of a defense by **[Plaintiffs' Proposed Language: a preponderance or]** greater weight of the evidence. I will instruct you on the facts they must prove for any affirmative defense. After considering all the evidence, if you decide that either defendant has successfully proven that the required facts are more likely true than not, the affirmative defense as to that defendant is proved.

You have probably heard the phrase “proof beyond a reasonable doubt.” That is a stricter standard than “more likely true than not true.” It applies only in criminal cases, but not in this civil case, so put it out of your mind.

**Plaintiffs’ Source(s):** 8TH CIR. CIVIL JURY INSTR. § 3.04 (2021), modified.

**Defendants’ Source(s):** 8TH CIR. CIVIL JURY INSTR. § 3.04. (2021).



**Plaintiffs' Statement in Support of Their Position**

Plaintiffs' proposed language is preferable because it includes the actual name of the burden of proof (i.e., "preponderance"), a term with which jurors may be familiar. Its exclusion may lead to confusion or inference of a higher burden. Plaintiffs provide a neutral and fair explanation of the quantum of evidence necessary for the United States to carry its burden. This explanation will assist the jury in its task of weighing the evidence at the close of trial.

Plaintiffs' proposed language referring to and explaining the "preponderance" standard and is further justified by Defendants' repeated reference to this standard by name in their proposed Closing Instruction Nos. 31D and 46D. The jury should be provided an explanation of this term.

**Defendants' Statement in Support of Their Position**

Defendants' proposed instruction, along with the final paragraph, are a verbatim statement of model Eighth Circuit Civil Jury Instruction § 3.04 (2021). The additional language proposed by Plaintiffs is a transparent effort to associate the United States with a "scale" of justice in jurors' minds. The language plays off cultural tropes depicting concepts such as "blind justice" and "scales of justice" that may influence jurors to make improper assumptions concerning the evidence in a manner favorable to the Government and are in any event more appropriate to a criminal trial.

**Closing Instruction No. 23**  
**Expert Opinion**

You [have heard] [are about to hear] testimony from [witness's name] who [testified] [will testify] to opinions and the reasons for the opinions. This opinion testimony is allowed because of the education or experience of this witness.

You should judge this opinion testimony just as you would any other testimony. You may accept it or reject it and give it the weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all other evidence in this case.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 3.05 (2021).

**Closing Instruction No. 24**  
**Election of Foreperson; Duty to Deliberate; Communications with Court;**  
**Cautionary; Unanimous Verdict; Verdict Form**

There are rules you must follow when you go to the jury room to deliberate and return with your verdict.

*First*, you will select a foreperson. That person will preside over your discussions and speak for you here in court.

*Second*, your verdict must be the unanimous decision of all jurors. Therefore, it is your duty, as jurors, to discuss this case with one another in the jury room. You should try to reach agreement, if you can do this without going against what you believe to be true.

Each of you must come to your own decision, but only after you have considered all the evidence, discussed the evidence fully with your fellow jurors, and listened to the views of your fellow jurors.

Do not be afraid to change your mind if the discussion persuades you that you should. But, do not come to a decision just because other jurors think it is right, or just to reach a unanimous verdict. Remember you are not for or against any party. You are judges of the facts. Your only job is to study the evidence and decide what is true.

*Third*, during your deliberations, including during any recess taken during deliberations, you must not, directly or indirectly, communicate with or provide any information to anyone by any means or by any medium, about anything relating to this case, until I accept your verdict and discharge you from further service in this case. As I have instructed repeatedly, you may not in any manner seek out or receive any information about the case from any source other than the evidence received by the court and the law

of the case I have provided to you. You are only permitted to discuss the case with your fellow jurors during deliberations because they have seen and heard the same evidence you have. In our judicial system, it is important that you are not influenced by anything or anyone outside of this courtroom. Otherwise, your decision may be based on information known only by you and not your fellow jurors or the parties in the case. This would unfairly and adversely impact the judicial process.

*Fourth*, if you need to communicate with me during your deliberations, send me a note signed by one or more of you. Give the note to the [marshal] [bailiff] [court security officer] and I will answer you as soon as I can, either in writing or here in court. While you are deliberating, do not tell anyone - including me - how many jurors are voting for any side.

*Fifth*, nothing I have said or done was meant to suggest what I think your verdict should be. The verdict is entirely up to you.

*Finally*, the verdict form is your written decision in this case. The form reads: [read form]. You will take this form to the jury room, and when you have all agreed on the verdict, your foreperson will fill in the form, sign and date it, and tell the [marshal] [bailiff] [court security officer] that you are ready to return to the courtroom.

**Source:** 8TH CIR. CIVIL JURY INSTR. § 3.07 (2021).

**Closing Instruction No. 25P**  
**Corporate Party and Agency**

Precision Lens is a corporation. The law regards a corporation as a person capable of suing and being sued. But business entities like Precision Lens may only act through natural persons, such as their directors, officers, employees, or other agents. The law, therefore, charges the defendants with the knowledge that comes to each of its agents through the performance of his or her respective duties. The defendants are held to have the combined knowledge that comes to them through their various officers, employees, or agents.

A business entity is also responsible for the unlawful acts of its officers, employees, or agents, even if those acts were against corporate policy, provided those acts are done within the scope of their authority and for the benefit of the company, as will usually be the case if an act is done in the ordinary course of one's employment or within the scope of the company's business. Any agent or employee of a corporation may bind the corporation by acts and statements made while acting within the scope of the authority delegated to the agent by the corporation, or within the scope of his duties as an employee of the corporation. Therefore, if you find that an employee, agent, or officer of Precision Lens violated the Anti-Kickback Statute and/or the False Claims Act, you must find that Precision Lens violated the Anti-Kickback Statute and/or the False Claims Act.

**Plaintiffs' Source(s):** 8TH CIR. CIVIL JURY INSTR. § 5.23 (2021), modified; Kevin F. O'Malley, et al., 3 FEDERAL JURY PRACTICE AND INSTRUCTIONS: Civil § 108.01 (6th ed. 2012); *Frank v. Dana Corp.*, 646 F.3d 954, 963 (6th Cir. 2011) (imputing corporation with knowledge of CEO and CFO and discussing cases); 11th Cir. Pattern Civil Jury Instructions § 3.2.2 (2021). *See also U.S. v. Basic Constr. Co.*, 711 F.2d 570, 573 (4th Cir. 1983) (discussing cases in the antitrust context and upholding jury instruction stating

that the corporation may be held criminally responsible for antitrust violations committed by its employees, even if such acts were against corporate policy).

**Closing Instruction No. 25D**  
**Agency**

Precision Lens is a company. A company acts only through its agents or employees and any agent or employee of a company may bind it by acts and statements made while acting within the scope of the authority delegated to the agent by the company, or within the scope of his or her duties as an employee of the company.

**Defendants' Source(s):** 8TH CIR. CIVIL JURY INSTR. § 5.23 (2021), modified.



**Closing Instruction No. 26P**  
**The Anti-Kickback Statute**

Before you heard testimony, I advised you that I am the judge of the law, and you, the jury, are the judges of the facts. So that you will have the framework provided by the laws in mind as you hear the attorneys make their closing arguments, I will now provide you with the law you will apply to the facts you find as you deliberate.

This is a case under the Anti-Kickback Statute and the False Claims Act. The United States alleges Precision Lens and Paul Ehlen violated the Anti-Kickback Statute and thereby caused certain ophthalmologists to submit claims for payment to Medicare rendered false or fraudulent under the False Claims Act due to defendants' Anti-Kickback Statute violation. I will first explain the Anti-Kickback Statute and then turn to the False Claims Act.

The Anti-Kickback Statute is a federal law that prohibits any person from knowingly and willfully paying or offering anything of value ("remuneration"), where at least one purpose of the remuneration is to induce the person to purchase, order, or arrange or recommend for the purchase or order of items or services, which may be paid in whole or in part by Medicare.

Remuneration. To prove the defendants offered or paid "remuneration" under the Anti-Kickback Statute, the United States must show that it was more likely than not that the defendants offered or provided ophthalmologists something of value. This includes any payment, discount, other benefit, or anything of value, in any form whatsoever, provided directly or indirectly, openly or secretly, in cash or in kind.

Inducement. Remuneration of any kind violates the statute if one purpose for that remuneration was to induce recommendations or orders for healthcare services. To offer or pay remuneration to induce referrals means to do so with intent to gain at least some influence over the reason or judgment of a person making recommendations or ordering decisions. The intent to gain such influence must have been at least in part the reason the remuneration was offered or paid. Therefore, the United States must prove that at least one purpose of the remuneration offered or paid by the defendants was the ordering, purchasing, arranging or recommending of items, such as IOLs or other surgical supplies, which may be paid for in whole or in part by Medicare.

If you find that the United States has shown that it is more likely than not that one purpose of the defendants' offers or provision of remuneration was to induce the ordering, purchasing, arranging, or recommending of IOLs or other surgical supplies distributed by the defendants, then the inducement element of the Anti-Kickback Statute has been met. This is so even if you believe there were other legitimate purposes for the remuneration, because it is not a defense that there might have been other reasons for the remuneration.

The United States does not have to establish that the only purpose—or even the primary purpose—of the remuneration was to induce the ordering, purchasing, arranging, or recommending of IOLs or other surgical supplies distributed by the defendants, so long as one purpose was to do so.

Whether any physician paid fair market value for the items and services the defendants provided may or may not be relevant to your decision and is for you to decide. It is not, however, a separate element of the Anti-Kickback Statute. Rather, neither a

legitimate business purpose nor a fair market value payment renders an improper payment legitimate if one of the purposes of payment was to induce referrals. However, if you find that the physicians did not pay fair market value for any items or services the defendants provided, you may properly infer that the defendants offered items or services in order to induce referrals because the absence of fair market value is properly seen as evidence of inducement.

Knowingly and willfully. “Knowingly and willfully” means the defendants were aware that their conduct was wrongful or unlawful. The United States does not need to establish that defendants specifically intended to violate the Anti-Kickback Statute.

**Plaintiffs’ Source(s):** 42 U.S.C. § 1320a-7b(b)(1), (2); *id.* at § 1320a-7b(g); Order Den. Defs.’ Mot. for Summ. J. (Dkt. #722) at 5-7, 17-18, 25-28; Order Den. Defs.’ Mot. to Dismiss (Dkt. #152) at 4-10; *United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, 853 F.3d 131, 135 (4th Cir. 2017) (“An AKS violation that results in a federal health care payment is a per se false claim under the FCA.”); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29–31 (1st Cir. 1989) (“Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.”); *United States v. Greber*, 760 F.2d 68, 69–72 (3d Cir. 1985) (holding that AKS is violated if “one purpose of the payment was to induce future referrals,” “even if the payments were also intended to compensate for professional services.”); *United States v. Hancock*, 604 F.2d 999, 1001–02 (7th Cir. 1979) (finding indictments “adequately allege[d] the crime of receiving kickbacks” in the form of “handling fees” despite defendants’ arguments that such fees were for the “services of obtaining, packaging, and sending the samples”) (applying 1972 version of Medicare AKS); *see also United States v. Borrasi*, 639 F.3d 774, 780–82 (7th Cir. 2011); *United States v. McClatchy*, 217 F.3d 823, 835 (10th Cir. 2000), *cert. denied*, 531 U.S. 1015 (2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.” (quoting 56 Fed. Reg. 35,952, 35,958 (July 29, 1991))); *United States ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at \*16 (N.D. Ill. July 23, 2013) (stating that the economic benefit that inured to the benefit of defendant’s son qualified as “remuneration” for purposes of AKS); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at \*7 (S.D. Ohio Dec. 18, 2008) (agreeing that “remuneration” includes

“anything of value in any form whatsoever.”); *Klaczak v. Consolidated Med. Transport*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006) (broadly construing remuneration to include “anything of value”); *United States v. Shaw*, 106 F. Supp. 2d 103, 114 (D. Mass. 2000) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.”); HHS-OIG Notice, *Publication of OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B*, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994) (“When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.”).

*United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 2012 U.S. Dist. LEXIS 48026 (S.D. Ohio Feb. 27, 2012) (rejecting argument that alleging fair market value of services is affirmative element of Relator’s case); OIG Supplemental Compliance Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005); *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 97 (3rd Cir. 2009) (discussing Stark Act regarding fair market value and noting, “a negotiated agreement between interested parties does not ‘by definition’ reflect fair market value”); *Rogan*, 459 F. Supp. 2d at 716 (N.D. Ill. 2006) (the fact-finder may infer that payments were intended to be kickbacks where recipient was grossly overpaid for any services rendered); *Am. Lith. Soc. v. Thompson*, 215 F. Supp. 2d 23, 27 (D.D.C. 2002) (“Payment exceeding fair market value is in effect deemed payment for referrals”); *United States ex rel. Obert-Hong v. Advocate Healthcare*, 211 F. Supp. 2d 1045, 1049, n.3 (N.D. Ill. 2002).

42 U.S.C. § 1320a-7b(b)(1), (2); *id.* § 1320a-7b(h) (“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”); Pub. L. No. 96-499 § 917 (1980) (adding phrase “knowingly and willfully” to AKS); H.R. Rep. No. 1167, 96th Cong. at 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (explaining that “knowingly and willfully” were added to AKS to avoid penalizing individuals “whose conduct, while improper, was inadvertent”); *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996) (stating that a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS, only know that his conduct was wrongful); *see also United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015); *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013); *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013) (“[AKS] Section 1320a-7b(h) clarifies that the Government is not required to prove actual knowledge of the [AKS] or specific intent to violate it...As applied to [defendant], the Government was only required to prove that [defendant] willfully solicited or received money for referring Medicare patients to [payor of kickbacks].”); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998).

**Closing Instruction No. 26D**  
**Overview of the False Claims Act and the Anti-Kickback Statute**

Plaintiffs' allegations against Defendants involve two separate, but related, statutes: the False Claims Act and the Anti-Kickback Statute. Below is a general overview of the statutes as they apply to this case, and the instructions that follow contain detailed information about the individual elements of each statute.

**The False Claims Act** (sometimes referred to as the "FCA") provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval by the government is liable to the United States.

**The Anti-Kickback Statute** (sometimes referred to as the "AKS") makes it unlawful to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part by Medicare or Medicaid.

**Defendants' Source(s):** Final Jury Instrs. at 6, *U.S. ex rel. Cairns v. DS Medical LLC*, No. 1:12-cv-00004 (E.D. Mo. 2017), ECF No. 422.

**Closing Instruction No. 27D**  
**You Must First Determine Whether There Was a Violation of the Anti-Kickback Statute**

To establish the alleged False Claims Act violation, the jury must find that a defendant caused false claims to be submitted to Medicare. In this case the Plaintiffs allege that claims submitted to Medicare were false because one or more Defendants violated the Anti-Kickback Statute. In a moment, I will instruct you on the elements necessary to establish a violation of that law.

For each Defendant, you must separately analyze each of the 250 alleged violations of the Anti-Kickback Statute, and, if you determine there was an Anti-Kickback Statute violation, then determine whether Defendants caused the submission of a false claim to Medicare that resulted from that violation of the Anti-Kickback Statute.

**Defendants' Source(s):** These instructions, as modified for the facts of this case, were offered by the Government in *U.S. ex rel. Health Dimensions Rehab., Inc. v. Rehabcare Group*. United States of America's Requested Jury Instr. at 40, *U.S. ex rel. Health Dimensions Rehab., Inc. v. Rehabcare Group*, No. 4:12-cv-00848 (E.D. Mo. 2013), ECF No. 435; *see also* Tr. of Jury Trial (ECF 861) at 2953, *U.S. ex rel. Lutz v. BlueWave Healthcare Consultants*, 9:14-cv-230 (D.S.C. 2018).

**Closing Instruction No. 28D**  
**Elements of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b)**

A violation of the Anti-Kickback Statute has three elements, which are:

- (1) The defendant knowingly and willfully offered or paid remuneration to a particular physician;
- (2) The remuneration was provided primarily in order to induce, and in exchange for, the physician's selection of an item or service from Precision Lens that was insured by Medicare; and
- (3) The item or service was covered, in whole or in part, by a federal health care program.]

**Defendants' Source(s):** This instruction is based on the Eighth Circuit's model instruction. 8th Cir. Manual of Model Crim. Jury Instr. § 6.42.1320.

**Closing Instruction No. 29D**  
**“Knowingly and Willfully” Defined**

An act is done “*knowingly*” under the Anti-Kickback Statute if it is done voluntarily and intentionally, and not because of a mistake or accident.

In order to act “*willfully*” a Defendant must act unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. The Defendant need not be aware of the specific law or rule that he or she may be violating.

In order to violate the Anti-Kickback Statute, it is not enough to covet the business of another, there must be some bad intent to violate the law. If the Defendant acted in good faith, the Defendant did not act “knowingly” or “willfully.”]

**Defendants’ Source(s):** The wording concerning “knowingly” is standard in AKS cases and was used in both *BlueWave* and *Cairns*. Tr. of Jury Trial (ECF 861) at 2950-51, *U.S. ex rel. Lutz v. BlueWave Healthcare Consultants*, 9:14-cv-230 (D.S.C. 2018); Final Jury Instrs. at 11, *Cairns*, No. 1:12-cv-00004.

Defendants’ proposed approach to “willfully” is consistent with the Eight Circuit’s decision in *U.S. v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) (upholding an instruction that “the word ‘willfully’ means unjustifiably and wrongfully, known to be such by the defendant”). The specific wording in the proposed instruction is taken from *BlueWave* and *Cairns*. Tr. of Jury Trial at 2950-51, *BlueWave*, 9:14-cv-230; Final Jury Instrs. at 11, *Cairns*, No. 1:12-cv-00004.

The Eighth Circuit Manual of Model Criminal Jury Instructions explains that the term “willfully” as used in the AKS connotes a heightened *mens rea* standard to capture conduct that is “**inevitably nefarious, that is, ‘obviously ‘evil’ or inherently ‘bad[.]’**”

A *mens rea* instruction more rigorous than the traditional rule was held appropriate based on the fact that “the literal language of the statute might otherwise encompass some types of innocent conduct.” *Id.* at 440. “[T]he elements ‘knowingly and willfully’ were added to the statute in 1980 to reflect congressional concern **‘that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent.’**” *Id.* at 440. Because “[o]nly conduct that is inevitably nefarious, that is, ‘obviously ‘evil’ or inherently ‘bad,’ “warrants the



**traditional presumption that anyone consciously engaging in it has fair warning of a criminal violation,”** (citing *Ratzlaf v. United States*, 510 U.S. 135, 146-48 (1994)), the Eighth Circuit “agree[d] with the district court’s decision to instruct the jury that the government must meet a heightened *mens rea* burden.” *Id.* at 440.

8th Cir. Manual of Model Crim. Jury Instr. § 6.42.1320, n.5.

*See In re EpiPen Direct Purchaser Litig.*, No. 20-cv-0827 (ECT/TNL), 2021 WL 147166, at \*13 (D. Minn. Jan. 15, 2021) (“Evidence of this mental state [wrongfulness] includes ‘acts that indicate an awareness of an exchange of money for an improper purpose, such as . . . efforts to conceal the nature and source of such payments.’” *Hall v. St. Jude Med. S.C., Inc.*, 326 F. Supp. 3d 770, 783 (D. Minn. 2018) (citation omitted)”).

*See also U.S. v. Goodwin*, 974 F.3d 872, 874 (8<sup>th</sup> Cir. 2020) (same); *U.S. v. McTizic*, 972 F.3d 994, 995-96 (8th Cir. 2020), *reh’g denied* (Oct. 2, 2020) (same); *U.S. v. Yielding*, 657 F.3d 688, 708 (8th Cir. 2011); 2B O’Malley et al., *Fed. Jury Prac. and Instr. – Crim.* § 70:07, notes on Eighth Circuit decisions (6th Ed., Aug. 2021 update).

The final paragraph of the proposed instruction is based on *Jain*. *U.S. v. Jain*, 93 F.3d at 440 (observing “good faith” negates knowledge and willfulness).

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**Closing Instruction No. 30D**  
**“Remuneration” Defined**

As used in relation to the Anti-Kickback Statute, the term “**remuneration**” includes any benefit, or anything of value, in any form or manner, provided directly or indirectly, overtly or covertly, in cash or in kind. Under the Anti-Kickback Statute, “remuneration” includes transfers of items or services for free or for other than “fair market value.”

**“Fair Market Value”:** “Fair Market Value” means the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm’s length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.

Your determination of what “fair market value” means will depend on the circumstances surrounding each alleged kickback. Experts knowledgeable in the appropriate area may help you determine the “Fair Market Value” of an item or service, but there can be wide differences of opinion with respect to “fair market value,” and no single formula can be applied across the board. As finders of fact, it is up to you to determine whether an expert’s determination of an item’s “fair market value” is correct or appropriate for the circumstances.

If the physician pays the Defendant an amount that you determine to be “fair market value” for an alleged kickback, then you cannot find the alleged kickback to be a violation of the AKS because there is no remuneration.

**Defendants’ Source(s):** The first paragraph of Defendants’ proposed instruction is taken verbatim from the trial in *Cairns*. Final Jury Instrs. at 11, Cairns, No. 1:12-cv-00004.

The definition of “Fair Market Value” is taken from the Int’l Glossary of Bus. Valuation Terms at 10 (Am. Inst. of Certified Public Accts. (Dec. 14, 2020) (defining “Fair Market Value”); *see also* *Armstrong v. Sabin*, No. 2:20-CV-261-TS-DAO, 2021 WL 3473256, at \*7 (D. Utah Aug. 6, 2021) (using an older version of this glossary to define “Fair Market Value”).

The determination of “Fair Market Value” is described by reference to Internal Revenue Service and U.S. Treasury Department rules: “A determination of fair market value, being a question of fact, will depend on the circumstance in each case.” Rev. Rul. 59-60, 1959-1 C.B. 237 at § 3.01 (discussing how to determine the fair market value of capital stock in closely held corporations—a notoriously difficult evaluation to make given the unavailability of market data). *Cf.* Rev. Rul. 59-60, 1959-1 C.B. 237 at § 3.01 (noting “No formula can be devised that will be generally applicable to the multitude of different valuations issues...Often, an appraiser will find wide differences of opinion...”).

**Closing Instruction No. 31D**  
**“To Induce” Defined**

“**To Induce**,” as that term is used in these instructions and under the Anti-Kickback Statute, means to attempt to gain influence over the reason or judgment of a person improperly or corruptly. The United States must prove by the greater weight of the evidence that remuneration was paid improperly or corruptly or explicitly as a quid pro quo in return for a decision to use Precision Lens’ products. The intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid.

When considering whether Plaintiffs have proven the elements of an Anti-Kickback Statute violation, it is not enough to show that Defendants provided remuneration—something of value—and at some later point in time physicians ordered Precision Lens products. Rather, Plaintiffs must prove that Defendants knowingly and willfully paid the physicians remuneration in return for the use of Precision Lens products in the treatment of Medicare patients.

**Defendants’ Source(s):** Jury instructions in *Ameritox v. Millennium Labs*, 8:11-cv-775-SCB-TBM, Dkt. 622, at 16-17 (M.D. Fla. June 16, 2014). *See* Eighth Circuit Pattern Jury Instruction, 6.42.1320 SOLICITING OR RECEIVING KICKBACKS IN CONNECTION WITH MEDICARE OR FEDERAL HEALTH CARE PROGRAM PAYMENTS (42 U.S.C. § 1320A7B(B)(1)(A)) (“The remuneration was **paid primarily in order to induce the referral** of a patient insured by Medicare.”) (emphasis added); *United States ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 699 (N.D. Miss. 2012) (“Indeed, in order to violate the AKS, it is not enough to covet the business of another, there must actually be **some bad intent to violate the law.**”) (citing *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir.1998) (emphasis added)).

*See also U.S. v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) (government must meet “heightened mens rea burden” because AKS potentially includes conduct that is not “inevitably nefarious”); *id.* at 442 (“The essence of a scheme to defraud is an intent to harm the victim. When there has been no actual harm, ‘the government must produce

evidence independent of the alleged scheme to show the defendant's fraudulent intent.'").

In the context of the AKS, to "induce" means to gain influence over another in order to execute a quid pro quo transaction. In *U.S. v. Reichel*, the court gave the following instruction:

"Induce" in this context means to undertake to gain influence over the judgment of the physician making a decision regarding the prescription and order of drugs. More specifically, as charged in this indictment, the contemplated inducement must be what is referred to as a quid pro quo ("this for that") transaction, one in which a person pays for meals or gives speaker payments (the "this") to a physician in exchange for the order or prescribing of Warner Chilcott drugs (the "that").

**In order to be a relevant inducement the remuneration must involve an intent to execute a quid pro quo transaction. A defendant cannot be convicted of the Anti-Kickback statute merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions.** If the remuneration is only for a purpose other than seeking to effect a quid pro quo transaction of payments of remuneration for order or purchase of drugs, it is not within the scope of the Anti-Kickback Statute. However, a defendant may act with a mixture of motives and the Government's burden is to prove that part of the remuneration is intended to compensate for past orders and/or induce future orders; but it is not required to prove that such compensation was the only reason for the remuneration.

Jury Instructions, *U.S. v. Reichel*, 1:15-cr-10324-DPW, p. 5-6, D. Mass. June 17, 2016.

This same logic concerning what qualifies as a relevant inducement for AKS liability applies in civil cases as well – only the government's burden of proof differs. See *Ameritox v. Millennium Labs.*, 8:11-cv-775-SCB-TBM, Dkt. 622, at 16 (M.D. Fla. June 16, 2014) (identifying as element of AKS violation that defendant paid physicians remuneration "to induce the doctor to refer to the provider as a quid pro quo a patient for a service covered by Medicare or Medicaid").

See also Jury Instructions, *U.S. v. Krikheli*, 1:08-cr-528-SLT, Dkt. 231, at 6 (E.D.N.Y. Aug. 18, 2011) ("In order to make out this element [solicitation or receipt of remuneration in return for purchase, leasing, etc.], the government must prove ... that the remuneration was solicited or received as a quid pro quo in return for the defendant taking one of the acts enumerated above. It is not necessary for the

government to prove that the defendant's receipt of remuneration was the only reason that the defendant acted. If you find that the remuneration was made for more than one purpose, it is sufficient for the government to prove ... that the receipt of remuneration was one reason that the defendant purchased ... any good, facility, service, or item.”).

The United States Department of Justice takes the position that the term “induce,” when used in a criminal statute such as the AKS, has an established meaning of “to entice or persuade another person to commit a crime.” *Petition for Writ for Certiorari* at 13-14, *United States v. Hansen*, cert. petition pending, No. 17-10548 (filed Aug. 25, 2022). The scope of criminal fraud statutes such as the AKS is generally limited to encompass corrupt acts so that the statute does not sweep in benign conduct. *See McDonnell v. U.S.*, 579 U.S. 550, 572-77 (2016); *U.S. v. Skilling*, 561 U.S. 358, 408-412 (2010); *U.S. v. Sun-Diamond Growers of Cal.*, 526 U.S. 398, 408-412 (1999). Moreover, the terms “kickback” and “bribe,” which are the relevant exemplars of “remuneration” stated in the AKS statutory text, and which qualify the phrase “to induce,” have well-established meanings, each of which involves a corrupting influence on the recipient. *Skilling*, 561 U.S. at 412-413.

**Closing Instruction No. 32D**  
**Remuneration Provided on Mere Expectation of Future Business Opportunity Does Not Violate the Anti-Kickback Statute**

It is not unlawful for a Defendant to hope or expect or believe that purchases would result from the payment of remuneration to a customer that was designed for other purposes. The mere expectation or hope of future profit or creation of a favorable business relationship does not violate the statute. A person does not violate the [AKS] by providing remuneration or other benefits solely as part of the routine cultivation of a business relationship rather than with the intent to induce specific purchases.

It is not illegal or improper for a company or individual to maximize profits. Neither the False Claims Act nor the Anti-Kickback Statute prohibits companies or individuals from seeking or earning profits, or seeking to maximize profits.

**Defendants' Source(s):** See O'Malley et al. 2B O'Malley et al., Fed. Jury Prac. and Instr. – Crim. § 70:06 (6th Ed., Aug. 2021 update) (“It is not unlawful to hope or expect or believe that purchases would result from the payment of remuneration to a customer that was designed for other purposes. The expectation of profit or creation of a favorable business relationship does not violate the statute[.]”); Jury Instructions, *U.S. v. Reichel*, 1-15-cr-10324 (D. Mass) (“A defendant cannot be convicted of the Anti-Kickback Statute merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions.”); Jury Instructions, *U.S. v. MacKenzie, et al.*, (D. Mass. July 9, 2004); *U.S. v. Krikheli*, 461 F. App'x 7, 10-11 (2d Cir. 2012) (government “was required to prove that any payments...were made to induce referrals in a *quid pro quo* transaction”); *cf. U.S. v. LaHue*, 261 F.3d 993, 1002-03 n.10 (10th Cir. 2001) (even under the restrictive “one-purpose” rule in the Tenth Circuit, “[defendants] cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law.”).

The second paragraph is taken from *Cairns* Final Jury Instrs. at 12, 12-cv-00004 (E.D. Mo. 2017), ECF No. 422. See *U.S. ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 520-21, 528, 532 (6th Cir. 2012); *U.S. ex rel. Perales v. St. Margaret's Hosp.*, 243

F. Supp. 2d 843, 849, 851 (C.D. Ill. 2003); *U.S. ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 952-54 (S.D. Tex. 2007), *aff'd*, 2008 WL 3244000 (5th Cir. Aug. 7, 2008).



**Closing Instruction No. 33P**  
**The False Claims Act: Introduction**

The False Claims Act authorizes the United States to recover damages caused by false or fraudulent claims for money or property of the United States. Under the False Claims Act and as relevant in this case, a “claim” is any request or demand for money where Medicare or any other federal healthcare program provides any portion of the money requested. In this case, the claims are the requests to Medicare for reimbursement submitted by certain ophthalmologists for fees associated with cataract surgeries.

To find the defendants liable under the False Claims Act, you must find that it was more likely than not that (i) they knowingly caused to be submitted false or fraudulent claims to Medicare; or (ii) they knowingly caused false records or statements to be made or used that were material to false or fraudulent claims for payment made to Medicare. A false record or statement includes those that omit information that would be material to Medicare’s decision to pay the claim.

**Plaintiffs’ Source(s):** 31 U.S.C. §§ 3729-30; Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 6 (D.S.C. May 8, 2013); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) (“[E]ach time [defendant] submitted to Medicare a UB–92/04 form asking for reimbursement for a prohibited referral, it was knowingly asking the government to pay an amount that, by law, it could not pay. Consequently, we find the district court did not err in finding that each UB–92/04 form constituted a separate claim.”); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 26 (E.D. Va. Aug. 1, 2014); *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (“[C]laim” under the False Claims Act refers to “all fraudulent attempts to cause the Government to pay out sums of money.”).

**Closing Instruction No. 33D**  
**Elements of the False Claims Act (31 U.S.C. § 3729(a)(1))**

If you find that either Defendant violated the Anti-Kickback as to an alleged kickback, and no defense or exception applies, you next must determine for that violation whether the Defendant also violated the False Claims Act.

To find a violation of the False Claims Act, you must determine by the greater weight of the evidence, as to each Defendant individually, that:

- (1) The Defendant caused to be presented a claim to the government for payment;
- (2) The claim would not have included particular items or services distributed by Precision Lens absent the illegal kickbacks, as defined in Defendants' Instruction Nos. 24 through 30;
- (3) The Defendant knew the claim was false or fraudulent; and
- (4) The false or fraudulent information in the claim was material to the government's decision to pay the claim.

To succeed on these claims, Plaintiffs must prove each of the elements by the greater weight of the evidence. If you find by the greater weight of the evidence that Defendants violated the False Claims Act, then you must determine how many claims Defendants caused to be submitted.

**Defendants' Source(s):** 31 U.S.C. §§ 3729-30. The first paragraph is taken from *U.S. v. BlueWave HealthCare Consultants et al.*, 9:14-cv-230 (D.S.C. 2018), ECF No. 861 (noting that the government must first prove all the elements of an AKS violation and then the elements of the FCA).

The instructions on the elements are taken from *Cairns*, except the second element is modified to reflect the Eighth Circuit’s rejection of the district court’s causation analysis. Final Jury Instrs. at 7, *Cairns*, No. 1:12-cv-00004 (E.D. Mo. 2017); *U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828, 837 (8th Cir. 2022) (“[T]he government had to prove here that the defendants would not have included particular ‘items or services’ [in the claim] absent the illegal kickbacks.”).

The paragraph regarding the burden of proof is also taken from *Cairns*, 42 F.4th at 833-34 (preponderance standard applies to AKS, even though it is a criminal statute, when pled as a predicate to civil FCA violation) and *U.S. v. Allquest Home Mortgage*, 4:12-cv-2676 (S.D. Tex. 2016), ECF No. 434, Jury Instrs. and Charge at 6.

**Closing Instruction No. 34P**  
**False or Fraudulent Claim/AKS Causation**

A claim is “false or fraudulent” if it seeks payment for services that are not payable by Medicare. To be “payable by Medicare” a claim must contain accurate and truthful information.

A claim is also false or fraudulent if it is submitted for payment in violation of material conditions of receiving payment from government healthcare programs. Compliance with the Anti-Kickback Statute is a material term of federal healthcare reimbursement. Claims submitted in violation of the Anti-Kickback Statute are not payable by federal healthcare programs.

A claim’s falsehood can be established by material omissions: For example, if a claim contains specific representations, like billing codes identifying goods or services as eligible for payment, and fails to disclose noncompliance with a material statutory requirement that makes those representations misleading, the claim is false or fraudulent. A claim need not contain express falsehoods to be false or fraudulent under the False Claims Act. Claims submitted for payment with billing codes for items and services associated with cataract surgeries that do not disclose that the underlying transaction did not comply with the Anti-Kickback Statute constitute false claims.

Everything that I have read to you thus far applies throughout the entire time period relevant to this case, January 1, 2006 through December 31, 2015.

After March 23, 2010, a claim’s falsehood also can be established through a new provision added to the Anti-Kickback Statute. Under that provision, a claim is false or

fraudulent if the claim includes items or services resulting from a defendant's violation of the Anti-Kickback Statute. This amendment creates a supplemental method for Plaintiffs to demonstrate falsity and causation under the Anti-Kickback Statute. Under this supplemental method, if you find a defendant violated the Anti-Kickback Statute, the claim is false if the kickback was a but-for cause of the recipient ophthalmologist's decision to use products supplied by defendants in cataract surgeries funded in whole or in part by Medicare. The violation alleged in this matter is the offer and payment of kickbacks with one purpose to use products distributed by defendants instead of their competitors in cataract surgeries, and that the resulting claims violated the Anti-Kickback Statute. The kickback can be one of a number of factors to produce the result; as long as it was one of the factors that led to the result, that is sufficient, even if it was just the proverbial straw that broke the camel's back. If liability is established under this method, false claims are presumed and you do not need to further consider the materiality of the violation.

Under the supplemental method, the United States may establish falsity by showing that the kickback was a but-for cause of the claim, or by showing that the claim failed to disclose that the underlying transaction did not comply with the Anti-Kickback Statute, a material condition of payment. It is not required to show both.

**Plaintiffs' Source(s):** 31 U.S.C. § 3729(a)(1)(A)-(B); *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975)(false certifications frustrate government "attempt to process only valid claims and led to the payment for services which were not covered or payable under the Act"); *United States ex rel. Lisitza v. Johnson & Johnson, Ortho-McNeil-Janssen Pharm., Inc.*, 765 F. Supp. 2d 112, 127 (D. Mass. 2011) (collecting cases holding compliance with AKS to be material to government decision to pay claims); *Thayer v. Planned Parenthood of the Heartland, Inc.*, 11 F.4th 934, 938 (8th Cir. 2021) (plaintiff must show "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.") (citing *Universal Health Servs., Inc. v.*

*United States ex rel. Escobar*, 579 U.S. 176, 136 S. Ct. 1989, 1996, 195 L. Ed. 2d 348 (2016) (addressing claim under § 3729(a)(1)(A)); *see also United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 503 (8th Cir. 2016) (applying same rule to claim brought under § 3729(a)(1)(B)). *United States v. Bos. Sci. Corp.*, No. 11-cv-2453 (JNE/TNL), 2021 U.S. Dist. LEXIS 152765, at \*19 (D. Minn. Aug. 12, 2021) (“[T]he False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions.”) (citing *Escobar*, 136 S. Ct. at 1999 (“where ‘a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.’”)).

*United States ex rel. Hutcheson v. Blackstone Medical*, 647 F.3d 377, 392-95 (1st Cir. 2011)(federal healthcare provider agreements establish that compliance with the AKS is a material condition of payment; knowing submission of claim to the United States while in violation of material conditions of payment violates the False Claims Act); *United States v. Rogan*, 517 F.3d 449, 452-53 (7th Cir. 2008); *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1269-70 (D.C. Cir. 2010); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002) (FCA violated by violations of “continuing duty to comply with the regulations on which payment is conditioned”); *cf. United States ex rel. Hobbs v. Medquest Assocs.*, 711 F.3d 707, 717 (6th Cir. 2013) (violations that do not naturally tend to influence CMS’s decision to pay on the claims are not actionable under the FCA).

*United States v. Rogan*, 459 F. Supp. 2d at 714, 717, 724 (“Falsely certifying compliance with the [AKS] in a Medicare cost report is actionable under the FCA”, and “compliance with the Anti-Kickback Statute is a condition of payment by the Medicare and Medicaid program...[The AKS] clearly provide[s] that compliance with [its] terms is a condition of payment under the Medicaid programs. The United States would not have paid the claims if it had known the claims were false (in claiming statutory compliance) because compliance with the...[AKS] is a statutory condition of payment.”); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (“Legion other cases [sic] have held violations of AKS...can be pursued under the FCA, since they would influence the Government’s decision of whether to reimburse Medicaid claims.”); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) (“Compliance with the AKS is thus central to the reimbursement plan of Medicare.”); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp.2d 28, 32 (D.D.C. 2003)); *United States ex rel. Nehls v. Omnicare, Inc. et al.* No. 07-C-05777, 2013 U.S. Dist. LEXIS 102543, at \*27-8, 2013 WL 3819671, at \*9-\*10 (N.D. Ill. July 23, 2013)(“compliance with the AKS...is a condition of reimbursement from Medicaid programs”); *United States ex rel. Walker v. R & F Props. of Lake County, Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 7 (S.D. Tex. Nov. 18, 2016); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (“By punishing

defendants who submit ‘false or fraudulent claims,’ the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions.”); *id.* (“[T]he term ‘fraudulent’ is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.”); *McNutt v. Haleyville Med. Supplier, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co.*, 321 F.3d 926, 933 (9th Cir. 2003); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999) (“The phrase ‘false or fraudulent claim’ in the False Claims Act should be construed broadly. The False Claims Act is ‘intended to reach all types of fraud, without qualification, that might result in financial loss to the Government...[T]he Court has consistently refused to accept a rigid, restrictive reading...” (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968))).

*Burrage v. United States*, 571 U.S. 204, 211 (2014) (but-for is not a narrow standard, “[t]he same conclusion follows if the predicate act combines with other factors to produce the result, so long as the other factors alone would not have done so—if, so to speak, it was the straw that broke the camel’s back. Thus, if poison is administered to a man debilitated by multiple diseases, it is a but-for cause of his death even if those diseases played a part in his demise, so long as, without the incremental effect of the poison, he would have lived.”); *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1739 (2020) (but-for “can be a sweeping standard...a defendant cannot avoid liability just by citing some other factor that contributed [to its action]”); *United States v. Cathey*, 997 F.3d 827, 833-34 (8th Cir. 2021) (but for means that the conduct need “only to be one link in the chain of events necessary for the injury...to occur.”); *Cincinnati Ins. Co. v. Rymer Co., LLC*, 41 F.4th 1026, 1029-30 (8th Cir. 2022) (under traditional but-for principles, event at issue properly sat in the causal chain even though the harm was also caused by another pre-existing condition).

*See also* Center for Medicare and Medicaid Services (CMS) Provider Agreement, Form 855 (institutional provider) and Form 855i (physician provider), in which every federal healthcare provider certifies, “I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).” This form was promulgated in 2001 and is available at <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf>; <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf>

*See also* Form 855b cited in *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002), available at <http://www.primarybilling.com/pdf/cms855b.pdf>.

*See also, e.g.*, Ctrs. for Medicare & Medicaid Servs., Form 1500: Health Insurance Claim Form, available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1188854>, and Ctrs. for Medicare & Medicaid Servs., Form 1450: UB-04 Uniform Bill (Rev. 03-07).



**Closing Instruction No. 35P**  
**Knowledge**

For purposes of the False Claims Act, the terms “knowing” and “knowingly” mean that a defendant, with respect to information:

- (1) had actual knowledge of the information; or
- (2) acted in deliberate ignorance of the truth or falsity of the information; or
- (3) acted in reckless disregard of the truth or falsity of the information.

The United States does not need to prove that any defendant specifically intended to defraud the government.

“Actual knowledge” means affirmative knowledge that the claims were false. The United States may establish that a defendant’s intent or knowledge through circumstantial evidence. For example, if it appears that a certain condition existed for a substantial period of time, and that defendant had regular opportunities to observe the condition, then you may draw the inference that the defendant had actual knowledge of the condition. It is reasonable to infer that a person intends the natural and probable consequences of acts knowingly done or knowingly not done.

“Knowledge” under the False Claims Act also includes acting in deliberate ignorance of the truth or falsity of the information. The United States can prove “deliberate ignorance” through proof that a defendant deliberately closed its eyes to clear warning signs or to what otherwise would have been obvious to it. A finding that a defendant purposely avoided learning all the facts, or suspected a fact but refused to confirm it, also

constitutes deliberate ignorance. Stated another way, a defendant's knowledge of a fact may be inferred from willful blindness to the existence of the fact.

"Knowledge" under the False Claims Act also includes acting in "reckless disregard" of a claim's truth or falsity. The United States can prove "reckless disregard" through proof that a defendant was reckless in determining whether a claim was true or false. An innocent mistake or mere negligence is not sufficient to constitute knowledge under the False Claims Act. A defendant acts with reckless disregard if they had reason to know of facts that would lead a reasonable person to realize they were causing the submission of a false claim or if the defendant failed to make a reasonable inquiry into that possibility.

**Plaintiffs' Source(s):** 31 U.S.C. § 3729(b)(1); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 11–12 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 38-41 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 6 (S.D. Tex. Nov. 18, 2016).

*United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 811–812 n.10 (10th Cir. 2002) (approving instruction that in considering whether defendant knowingly made any false statements, jury "must consider all direct and circumstantial evidence"); *Jones v. Otis Elevator Co.*, 861 F.2d 655, 661 n.11, 665 (11th Cir. 1988) (approving instruction that "[k]nowledge or notice may also be established by circumstantial evidence. If it appears that a certain condition has existed for a substantial period of time and that the defendant had regular opportunities to observe the condition, then you may draw the inference that he had knowledge of the condition"); *see also United States v. Mallen*, 843 F.2d 1096, 1099 (8th Cir. 1988); *United States v. Wetzel*, 514 F.2d 175, 177-78 (8th Cir. 1975).

S. Rep. No. 99-345, at \*7, 21 (1986); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001-02 (2016) ("[B]ecause a reasonable person would realize the imperative of a functioning firearm [when the Government orders guns], a defendant's failure to appreciate the materiality of that condition would amount to 'deliberate ignorance' or 'reckless disregard' of the 'truth or falsity of the information' even if the Government did not spell this out."); *Tuomey*, 792 F.3d at 380 ("The purpose of the

FCA’s scienter requirement is to avoid punishing ‘honest mistakes or incorrect claims submitted through mere negligence.’”) (quoting *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010)), at 382 (“warnings” and “subsequent inaction” are probative of knowledge); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (“Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.”); *id.* at 828 (“[Defendant’s] claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of those requirements, particularly when twenty percent of [his clinic’s] patients were Medicare beneficiaries, he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.”); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass 2008) (“[H]aving entered into the rebate agreements, the defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program,” including “the procedures and legal requirements applicable to reimbursements”); *United States ex rel. Ervin & Assocs. v. Hamilton Secs. Grp., Inc.*, 370 F. Supp. 2d 18, 41–42 (D.D.C. 2005) (defendant must make “such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim”).

*United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) (“[FCA plaintiff] need only show that [defendant] had reason to know of facts that would lead a reasonable person to realize that [defendant] was causing the submission of a false claim . . . or that [defendant] failed to make a reasonable and prudent inquiry into that possibility . . . .”); *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) (“[FCA] defines reckless disregard as an extension of gross negligence.”).

**Closing Instruction No. 35D**  
**Knowledge**

For purposes of the False Claims Act, the terms ‘knowing’ and ‘knowingly’ mean that the defendant (1) acted with actual knowledge of the claim's falsity, or (2) acted in deliberate ignorance of the claim's falsity, or (3) acted in reckless disregard of the claim's falsity. The United States does not need to prove that any defendant specifically intended to violate the False Claims Act; however, mere errors or negligence are not enough to create liability under the False Claims Act.

“‘*Knowingly*’ or ‘*knew*’ as used above means that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information; and requires no proof of specific intent to defraud.

‘*Actual knowledge*’ means affirmative knowledge that the claims were false.

‘*Deliberate ignorance*’ means that a defendant deliberately closed its eyes to clear warning signs or to what otherwise would have been obvious to it. It also includes situations where a defendant purposely avoided learning all the facts, or suspected a fact but refused to confirm it.

‘*Reckless disregard*’ means that a defendant was reckless in determining whether a claim was true or false. An innocent mistake or mere negligence is not sufficient to constitute knowledge under the False Claims Act. But if a defendant failed to make such inquiry as would be reasonable and prudent, that is evidence of ‘reckless disregard.’”

**Defendants' Sources:** *U.S. v. BlueWave HealthCare Consultants et al.*, 9:14-cv-230 (D.S.C. 2018), ECF No. 861; Final Jury Instrs. at 7-8, *Cairns*, No. 1:12-cv-00004 (E.D. Mo. 2017); see also Statement in Support, below.

**Closing Instruction No. 36P**  
**Submitter of Claim**

A person need not be the one who actually submitted the claim forms in order to be liable under the False Claims Act. That is to say, it is not necessary for a defendant to prepare the claim or receive the money directly from the Government; the defendant's causing the payment of government money to some other individual or entity will suffice. The False Claims Act applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud, without regard to whether that person has direct contractual relations with the government.

**Plaintiffs' Source(s):** *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544–45 (1943) (“[FCA] reach[es] any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government.”); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (“We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party.”); *United States v. Hawley*, 619 F.3d 886, 892 (8th Cir. 2010); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (“The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud, without regard to whether that person has direct contractual relations with the government.” (quotation marks omitted)); *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (“The FCA places liability not only on persons who cause false claims to be submitted...but also on those who cause the claims...to be false in the first place.” (citing 31 U.S.C. §§ 3729(a)(1), (a)(2))); *United States v. Bos. Sci. Corp.*, No. 11-cv-2453 (JNE/TNL), 2021 U.S. Dist. LEXIS 152765, at \*18-19 (D. Minn. Aug. 12, 2021) (“Claims under the statute include ‘direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs.’”) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, (2016)).

**Closing Instruction No. 37P**  
**FCA Causation**

The United States may show Defendants “caused” a false claim under the False Claims Act by proving Defendants’ conduct was a substantial factor in bringing about the submission of the claim and such submission was a foreseeable consequence of the Defendants’ conduct.

**Plaintiffs’ Source(s):** 31 U.S.C. § 3729(a)(1)(A), (B); Order Den. Defs.’ Mot. for Summ. J. (Dkt. #722) at 28-30; *Peterson v. Weinberger*, 508 F.2d 45, 52-53 (5th Cir. 1975); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-245 (3d Cir. 2004); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 37 (E.D. Va. Aug. 1, 2014); *United States v. Bornstein*, 423 U.S. 303, 313 (1976); *In re Baycol Products Litig.*, 732 F.3d 869, 877-78 (8th Cir. 2013); *United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 714–15 (7th Cir. 2013) (applying in FCA case “traditional, time-tested notions of [proximate] causation” as “that which, in a natural and continuous sequence, unbroken by any efficient intervening cause, produces the injury and without which the result would not have occurred”); *United States ex rel. Cairns v. D.S. Medical*, 42 F.4th 828, 836 (8th Cir. 2022).

**Closing Instruction No. 38P**  
**Materiality**

Under the False Claims Act, the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

A matter is material if a reasonable person would attach importance to it in determining his or her choice of action, or if the defendant knew or had reason to know that the Government attaches importance to the matter.

Compliance with the Anti-Kickback Statute is a material term of federal healthcare reimbursement.]

**Plaintiffs’ Source(s):** 31 U.S.C. § 3729(b)(4); 42 U.S.C. § 1320a-7b(g); Order Den. Defs.’ Mot. for Summ. J. (Dkt. #722) at 22, n. 5; *Thayer v. Planned Parenthood of the Heartland*, No. 4:11-cv-129-JAJ, 2019 U.S. Dist. LEXIS 239542, at \*45 (S.D. Iowa Apr. 1, 2019) (“The term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”) (citing 31 U.S.C. § 3729(b)(4)); *United States v. Bos. Sci. Corp.*, No. 11-cv-2453 (JNE/TNL), 2021 U.S. Dist. LEXIS 152765, at \*19 (D. Minn. Aug. 12, 2021) (same); *United States ex rel. Johnson v. Golden Gate Nat’l Senior Care, L.L.C.*, No. 08-1194 (DWF/HB), 2020 U.S. Dist. LEXIS 68909, at \*8 (D. Minn. Apr. 20, 2020) (same).

*United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002–03 (2016) (explaining, by reference to the common law, that a matter is material: “(1) if a reasonable man would attach importance to it in determining his choice of action in the transaction; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, even though a reasonable person would not” (quotation marks and alterations omitted)); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 503 (8th Cir. 2016) (citing same); *Escobar*, 136 S. Ct. at 2003 (“[A]n undisclosed fact was material because [n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood of the undisclosed fact.” (quotation marks omitted)); *Escobar*, 136 S. Ct. at 2003 (noting violation of collusive bidding requirement was material because “the government’s money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive” (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943))); *Neder v. United States*, 527 U.S. 1, 16 (1999) (“In general, a false statement is material if it has a natural tendency to influence, or is capable of influencing, the decision of the decision-making body to which it was



addressed.” (quotation marks omitted)); *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017) (“Guns that do not shoot are as material to the Government’s decision to pay as guards that cannot shoot straight.”); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 914, 916–17 (4th Cir. 2003) (“Courts give effect to the FCA by holding a party liable if the false statement it makes . . . has a natural tendency to influence or is capable of influencing the government’s funding decision, not whether it actually influenced the government not to pay a particular claim.”).

**Closing Instruction No. 39D**  
**Definitions of Terms Related to the False Claims Act**

As used in relation to the False Claims Act, the terms below are defined as follows:

**“Claim”**: In this case, a “claim” is the facility fee and the professional fee submitted for each surgery.

**“False or Fraudulent”**: A claim for Medicare reimbursement is “false or fraudulent” if it includes items or services resulting from a violation of the Anti-Kickback Statute.

**“Caused to be Presented”**: To show that a Defendant caused a claim to be presented, as used above, the Government must prove that a claim resulted from a Defendant’s violation of the Anti-Kickback Statute. That is, the Government must show that the claim would not have included particular items or services absent a Defendant’s payment of an illegal kickback to the surgeon. It is not enough for the United States to show that a kickback may have been a contributing factor to the submission of a claim, or that the submission of a claim occurred near in time to the kickback. Nor is it enough for the United States to show that a claim failed to disclose a kickback violation. Instead, the United States must show that a particular surgery would not have been performed, or a particular lens or other items would not have been used, but for the kickback.

**“Material”**: The False Claims Act defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” Plaintiffs are required to prove that Defendants knowingly violated a requirement that Defendants knew was material to the government's payment decision. This is a demanding

requirement, and Plaintiffs are required to show more than minor or insubstantial regulatory violations.

**Defendants’ Sources: Source for claim paragraph:** *U.S. ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. CV 11-1210, 2018 WL 4604307, at \*4 (D.N.J. Sept. 24, 2018) (“Thus, the Form 1500 represents a claim, regardless of the number of diagnostic codes or line entries included on each form.”); *U.S. v. Krizek*, 111 F.3d 934, 943 (D.C. Cir. 1997) (“We also hold that the ‘claim’ in this context is the HCFA 1500 form.”).

**Source for False or Fraudulent and Caused to Be Presented paragraphs:** 42 U.S.C.A. § 1320a-7b(g); *U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828, 835 (8th Cir. 2022) (government can only recover for “harm [that] would not have occurred in the absence of – that is, but for – the defendant’s conduct”).

**Source for Materiality paragraph:** 31 U.S.C. § 3729(b)(4); *U.S. ex rel. Johnson v. Golden Gate Nat’l Senior Care, L.L.C.*, 223 F. Supp. 3d 882, 891 (D. Minn. 2016); *see also Thayer v. Planned Parenthood of the Heartland, Inc.*, 11 F.4th 934 (8th Cir. 2021) (holding that a relator must show that “the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.”) (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016) (“The materiality standard is demanding. The False Claims Act is not an ‘all-purpose antifraud statute’ or a vehicle for punishing garden-variety breaches of contract or regulatory violations. . . . Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.”).); *see also Golden Gate*, 223 F. Supp. 3d at 890–91.

**Closing Instruction No. 40**  
**Joint and Several Liability**

Under the False Claims Act, defendants are jointly and severally liable. That means that the United States can recover the total sum of damages only once from any or both of the defendants whom you find have violated the False Claims Act. Thus, if you find that the defendants violated the False Claims Act, you should determine the amount of damages for which each defendant may be responsible. If you find that each defendant is responsible for the same damages, you should not concern yourself with how the damages are apportioned between the defendants; that is the Court's job.

**Sources:** *United States v. Cooperative Grain & Supply Co.*, 476 F.2d 47, 64 (8th Cir. 1973) (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 552 (1942); *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959).

**Closing Instruction No. 41P**  
**Good Faith Reliance on Advice of Counsel**

Each defendant has asserted an affirmative defense of good faith reliance on the advice of counsel. You may consider the advice given by counsel to a defendant in deciding whether the defendant acted knowingly and willfully if you find that, before taking action, the defendant:

(1) in good faith sought the advice of an attorney whom the defendant considered competent for the purpose of securing advice on the lawfulness of the defendant's possible future conduct;

(2) made a full and accurate report to the attorney of all material facts which the defendant knew; and

(3) acted strictly in accordance with the advice of the attorney who had been given a full report.

The mere fact of consulting an attorney is insufficient. Furthermore, the attorney consulted must be disinterested and independent. In determining whether a defendant reasonably relied on the advice of its counsel, you may consider all the advice given to a defendant by any source.

**Plaintiffs' Source(s):** *United States v. Joshua*, 648 F.3d 547, 554 (7th Cir. 2011); *United States v. Rice*, 449 F.3d 887, 896–97 (8th Cir. 2006) (“[A] defendant is not immunized from criminal prosecution merely because he consulted an attorney in connection with a particular transaction.”), *cert. denied*, 549 U.S. 1040 (2006); *see also Williamson v. United States*, 207 U.S. 425, 453 (1908) (“[N]o man can willfully and knowingly violate the law and excuse himself from the consequences there of by pleading that he followed the advice of counsel.”); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 381 (4th Cir. 2015) (“[I]n determining whether [defendant] reasonably relied on the advice of its counsel, the jury was entitled to consider *all* the advice given to [defendant] by *any* source.” (emphasis in original)); *id.* at 381 (“[C]onsultation with a lawyer confers

no automatic immunity from the legal consequences of conscious fraud.” (quoting *United States v. Painter*, 314 F.2d 939, 943 (4th Cir. 1963), *cert. denied*, 374 U.S. 831 (1963)); *United States v. Nordbrock*, 38 F.3d 440, 445–46 (9th Cir. 1994); *United States v. Benson*, 941 F.2d 598, 614 (7th Cir. 1991) (“[T]o negate willfulness counsel’s advice must create (or perpetuate) an honest misunderstanding of one’s legal duties. If a person is told by his attorney that a contemplated course of action is legal but subsequently discovers the advice is wrong or discovers reason to doubt the advice, he cannot hide behind counsel’s advice to escape the consequences of his violation.”), *modified*, 957 F.2d 301 (7th Cir. 1992); *SEC v. O’Meally*, 06 CIV 6483 LTS RLE, 2010 WL 3911444, at \*4 (S.D.N.Y. Sept. 29, 2010) (citing, *inter alia*, *C.E. Carlson, Inc. v. SEC*, 859 F.2d 1429, 1436 (10th Cir.1988)) (counsel consulted must be disinterested and independent); *Sorrell v. SEC*, 679 F.2d 1323, 1327 (9th Cir. 1982) (may not rely on counsel’s advice where attorney is interested party).

**Closing Instruction No. 41D**  
**Advice of Counsel**

One of the issues in this case is whether the defendants in good faith followed the advice of their counsel, that is, their attorneys. Advice of counsel is a circumstance that may be considered by you in determining whether the defendant acted in good faith and lacked intent or willfulness. The defendant does not act with intent to defraud or willfully if (1) before taking action with regard to the alleged offense, the defendant in good faith consulted an attorney whom the defendant considered competent; (2) the defendant's consultation with the attorney was for the purpose of securing advice on the lawfulness of the defendant's possible future conduct; (3) the defendant made a full and accurate report to the attorney of all material facts known to the defendant; and (4) the defendant then acted strictly in accordance with the advice the attorney gave. Whether the defendant in good faith followed the advice of counsel by meeting all four of these requirements is for you to determine.

**Defendants' Source(s):** 8th Cir. Manual of Model Crim. Jury Instr. § 9.09.

**Closing Instruction No. 42D**  
**Good Faith Is a Complete Defense to the Anti-Kickback Statute and the False Claims Act**

One of the issues in this case is whether Defendants acted in good faith. Good faith is a complete defense to the Plaintiffs' claims under the AKS and the FCA if Defendants did not act with the intent to defraud, which is an element of both the AKS and the FCA. The essence of the good faith defense is that one who acts with honest intentions cannot be convicted of a violation requiring fraudulent intent.

Good faith includes, among other things, an opinion or belief that is honestly held, even if the opinion is in error or the belief is mistaken. However, even though a defendant honestly held a certain opinion or belief, a defendant does not act in good faith if he or she also knowingly made false or fraudulent representations or promises, or otherwise acted with the intent to defraud or deceive another. Proof of fraudulent intent requires more than proof that a defendant only made a mistake in judgment or management, or was careless.

Plaintiffs have the burden of proving by the greater weight of the evidence that Defendants acted with the intent to defraud. Evidence that Defendants acted in good faith may be considered by you, together with all the other evidence, in determining whether or not Defendants acted with the intent to defraud.]

**Defendants' Source(s):** 8th Cir. Manual of Model Crim. Jury Instr. § 9.08A. See also O'Malley et al. in 2B O'Malley et al., Fed. Jury Prac. and Instr. – Crim. § 70:08 (6th Ed., Aug. 2021 update); *Jain*, 93 F. 3d at 440; 2B O'Malley et al., Fed. Jury Prac. and Instr. – Crim. § 70:08 Notes (6th Ed., Aug. 2021 update); *see also* Tr. of Jury Trial at 2951, *BlueWave*, 9:14-cv-230 (D.S.C. 2018); Final Jury Instrs. at 23, *Cairns*, No. 1:12-cv-00004 (E.D. Mo. 2017); *U.S. ex rel. Jamison v. McKesson Corporation*, 900 F. Supp. 2d 683, 698 n.7 (N.D. Miss. 2012); *U.S. ex rel. Sharp v. Consolidated Medical Transport, Inc.*, No. 96 CV 6502, 2001 WL 1035720, at \*10 (N.D. Ill. 2001).



**Closing Instruction No. 43D**  
**Good Faith Reliance on Legal Opinions and Other Advice**

A defendant who acts with a good-faith belief that his or her conduct is lawful does not willfully violate the Anti-Kickback Statute even if that belief is mistaken. Good faith has no precise definition, but it encompasses, among other things, a reasonable belief or opinion honestly held and an absence of malice or ill will.

In determining whether a defendant acted in good faith, you must consider the totality of the evidence presented. This includes all of the legal opinions and advice received by or known to the defendant, regardless of the source, to determine whether the defendant acted in good faith.]

**Defendants' Source(s):** Transcript of Jury Trial (ECF 861) at 2951, *U.S. ex rel. Lutz v. BlueWave Healthcare Consultants*, 9:14-cv-230 (D.S.C. 2018); *U.S. v. Hagen*, No. 3:19-CR-0146-B, 2021 WL 2255983, at \*4 (N.D. Tex. June 3, 2021) (permitting defendants to call attorneys to testify as to issue of defendants' good faith, despite not allowing defendants to assert an advice of counsel defense); *U.S. v. Mallory*, 988 F.3d 730, 739 (4th Cir. 2021) (approving jury instruction (in BlueWave) that, in determining whether defendants acted in good faith, the jury was to also consider "all of the legal opinions and advice received by or known to the defendant, regardless of the source[.]").

**Closing Instruction No. 44P**  
**Measure of Damages**

The measure of the Government's damages under the False Claims Act is the amount of money that the Government paid out by reason of the false claims. For any false claim you find here, the amount that Medicare paid is the amount of damages. This is so because the federal healthcare programs are, essentially, federal subsidies with conditions. Contractors who seek to be paid for products or services by a federal healthcare program must certify that they will abide by those conditions. Therefore, when one of those material conditions of payment is not met, nothing is due.

The United States is not required to prove that it was actually harmed by the submission of any false or fraudulent claims. Nor is it required to prove that any patient was harmed or did not receive the services or products billed for. Neither is the United States required to prove that the surgeries were necessary, and it is not a defense to the Anti-Kickback Statute or the False Claims Act that patients received good care or any care at all.

The value of the medical services the ophthalmologists provided is not relevant to the determination of the Government's damages. This means you are not to deliberate or attempt to calculate the value of any such services or products used, whether they were actually provided, or the quality or necessity of the services. You need only calculate the amount of claims the Government paid the ophthalmologists for false claims the defendants caused to be submitted, should you find that the defendants violated the False Claims Act. There will be a space in the verdict form for you to place this amount.]

**Plaintiffs’ Source(s):** 31 U.S.C. § 3729; Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 14 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 55 (E.D. Va. Aug. 1, 2014); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386–87 (4th Cir. 2015) (“By reimbursing [defendant] for services that it was legally prohibited from paying [under the Stark Law], the government has suffered injury equivalent to the full amount of the payments.”); *United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, No. 4:12-CV-00848-AGF, 2013 WL 5340910, at \*1 (E.D. Mo. Sept. 23, 2013) (“the Government may recover the full amount billed for the therapy services that allegedly violated the Anti-Kickback Statute, and is neither limited to—nor required to present evidence of—the amount by which the amount billed exceeded the fair market value of the services provided.”); *United States v. Rogan*, 459 F. Supp. 2d 692, 726 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449, 453 (7th Cir. 2008) (“The government offers a subsidy (from the patients’ perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [the provider] received on these [false claims] claims must be paid back.”); *See also United States ex rel. Compton v. Midwest Specialties*, 142 F.3d 296, 304 (6th Cir. 1998) (measuring damages by full contract price is not erroneous); *United States ex rel. Roby v. Boeing*, 302 F.3d 637, 648 (6th Cir. 2002) (measure of damages is full contract price when contractor submits claims which do not meet the contracted specifications); *United States ex rel. Emanuele v. Medicor Assocs.*, 2017 WL 4867614, at \*10 (W.D. Pa. Oct. 26, 2017) (ruling that the proper measure of damages was the full amount of the government payments for services that it was legally prohibited from paying due to illegal referrals or kickbacks).

*See also United States v. Mackby*, 339 F.3d 1013, 1018–19 (9th Cir. 2003) (in False Claims Act based on Medicare fraud, because the defendant was ineligible to bill Medicare the United States’ damages were found to be the sum of money that Medicare paid out even though the services for which reimbursement was claimed were actually performed); *United States ex rel. Freedman v. Suarez-Hoyos*, No. 8:04-CV-933-T-24, 2012 WL 4344199, at \*4 (M.D. Fla. Sept. 21, 2012) (same); *United States ex rel. Antidiscrimination Ctr. of Metro New York, Inc. v. Westchester County*, No. 06 Civ. 2860, 2009 WL 1108517, at \*3 (S.D.N.Y. Apr. 24, 2009) (rejecting “benefit of the bargain” theory where government provided a subsidy premised on certification of compliance); 3C Fed. Jury Prac. & Instr. § 178.60 (5th ed.); *United States v. Neifert-White*, 390 U.S. 228, 232 (1968); *Roby*, 302 F.3d at 646 (“FCA damages ‘typically are liberally calculated to ensure that they afford the government complete indemnity for the injuries done it.’” (citations omitted)).

**Closing Instruction No. 44D**  
**Actual Damages Under the False Claims Act**

Under the False Claims Act, the measure of the United States’ damages is the amount that it paid out for the claims deemed false over and above what it would have paid if the claims had been truthful.]

**Defendants’ Source(s):** 31 U.S.C. § 3729(a). Defendants’ Proposed Instruction is based on 3C O’Malley, Grenig & Lee, Fed. Jury Prac. and Instr. – Civil, § 178:60 (6th Ed. Aug. 2021 update). This is the standard approach for damages in an FCA case in the Eighth Circuit, which follows a “benefit of the bargain” approach: “The measure of the government’s damages would be the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.” *U.S. v. Coop. Grain & Supply Co.*, 476 F.2d 47, 62 (8th Cir. 1973); *see In re Baycol Prods. Litig.*, 732 F.3d 869, 874 (8th Cir. 2013) (“The FCA is not concerned with regulatory noncompliance, but with false or fraudulent claims that cause the Government to pay money.” (quotation omitted)); *U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828, 835 (8th Cir. 2022) (government can only recover for “harm [that] would not have occurred in the absence of – that is, but for – the defendant’s conduct”); *see also U.S. v. Bornstein*, 423 U.S. 303, 317, n.13 (1976) (the Government is entitled to receive damages under the FCA “equal to the difference between the market value [of the item] it received and retained, and the market value it would have received if they had been of the specified quality.”).

The FCA expressly provides that a violator may be liable only for the “amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a) (2008). Hence, multiple other courts have followed the “benefit of the bargain” model to identify actual damages in an FCA case. *See, e.g.,* Ct.’s Charge to Jury at 8, Abbott, 3:06-cv-01769-M (N.D. Tex. 2016); Jury Instrs. at 50, *Birkart*, No. 1:02-cv-1168 (E.D. Va. 2014); Ct.’s Instr. to Jury at 18, *U.S. ex rel. Gonzalez v. Fresenius*, 3:07-cv-00247 (W.D. Tex. 2010); *see also United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 922–23 (4th Cir.2003) (“the amount of money the government paid by reason of the false statements over and above what it would have paid absent the false statement”), *followed by United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group*, 370 F.Supp.2d 18, 55 (D.D.C.2005) (Oberdorfer, J.); *United States v. Mackby*, 339 F.3d 1013, 1018 (9th Cir. 2003), *cert. denied* 541 U.S. 936 (2004) (“Ordinarily the measure of the government’s damages under the FCA would be the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.” (citation omitted)).

**Closing Instruction No. 45**  
**Proof of Damages**

The fact I have instructed you as to the proper measure of damages should not be considered as indicating any view of mine as to which party is entitled to your verdict in this case. The United States must prove its damages by a preponderance of the evidence. As I instructed at the outset, this means the United States must prove to you, in light of all the evidence, that what it claims is more likely so than not so.

**Source(s):** 31 U.S.C. § 3731(d); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 14 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 51 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 8 (S.D. Tex. Nov. 18, 2016); *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390–91 (1983); 3 O’Malley et al., Fed. Jury Prac. and Instr. – Civil § 106:02 (6th ed., Aug. 2021 update); *see also* 5th Cir. Pattern Jury Instr. (Civil Cases) 15.1 (2020).

**Closing Instruction No. 46P**  
**Reasonable Certainty**

The United States is entitled to all damages it can prove with “reasonable certainty.” On the one hand, reasonable certainty does not require proof of damages with mathematical precision. Mere difficulty in ascertaining damages is not fatal to the United States. On the other hand, the United States is not entitled to speculative damages; that is, you should not award any amount for injury or damage, which, although possible, is wholly remote or left to conjecture.

**Plaintiffs’ Source(s):** *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264–66 (1946); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 51 (E.D. Va. Aug. 1, 2014); *Nat’l Farmers’ Org., Inc. v. Associated Milk Producers, Inc.*, 850 F.2d 1286, 1293 (8th Cir. 1988); *Miller v. Holzmann*, 563 F. Supp. 2d 54, 108 (D.D.C. 2008) (stating principle in FCA case), *vacated in part on unrelated grounds*, 608 F.3d 871 (D.C. Cir. 2010).

**Closing Instruction No. 46D**  
**Reasonable Certainty**

The United States must prove their damages with reasonable certainty. You may only award the United States damages that are not speculative. Speculative damages are those that might be possible but are remote or based on guesswork.

If you should find that the United States is entitled to a verdict, you may award the United States only such damages as will reasonably compensate it for such injury and damage as you find, from a preponderance of evidence in the case, the United States has sustained as a proximate result of the Defendants' conduct.

The United States is not required to prove the exact amount of its damages, but must show sufficient facts and circumstances to permit you to make a reasonable estimate of the damages. If the United States fails to do so, then it cannot recover.]

**Defendants' Source(s):** Jury Instruction 46, *U.S. ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 52 (E.D. Va. Aug. 1, 2014) (case cited by Government in its proposed instruction 7.3).

**Closing Instruction No. 47P**  
**Number of False Claims**

If you find that one or more defendants violated the False Claims Act, you must determine the number of false or fraudulent claims for which each defendant is responsible.

**Plaintiffs' Source(s):** 31 U.S.C. § 3729(a)(1); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 15 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 53 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 7 (S.D. Tex. Nov. 18, 2016); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 552 (1943); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015); *United States v. Bornstein*, 423 U.S. 303, 309 n.4 (1976) (stating the number of penalties is generally set at the number of individual false claims the defendant submitted to the government).



**Closing Instruction No. 47D**  
**You Must Determine the Number of False Claims**

If you find one or more Defendants liable under the False Claims Act, then you must determine, if you can without speculating, the number of false “claims” the Defendant submitted or caused to be submitted, regardless of whether you find that the United States was damaged as a result.

**Defendants’ Source(s):** 31 U.S.C. § 3729(a). This paragraph is taken verbatim from *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 53 (E.D. Va. Aug. 1, 2014).

**Closing Instruction No. 48D**  
**The Special Verdict Form**

For each Defendant, you must separately analyze each alleged instance of remuneration paid or provided to each physician. You must then separately determine whether each of these individual instances of remuneration violated the Anti-Kickback Statute, and, if so, whether it also violated the False Claims Act. You must then separately determine the amount of damages resulting from each alleged kickback that you find violated both the AKS and the FCA.

To assist in this highly individualized process, you will be provided with a Special Verdict Form. This form lists out each of the individual alleged remunerations paid or provided to each of the individual physicians. This form will assist you in making your separate analysis regarding whether the AKS and the FCA were violated, and what the applicable damages are, if any.

**Closing Instruction No. 49P**  
**Relator's Share**

Because the False Claims Act was designed to encourage ordinary citizens to assist the government in rooting out fraud, and because the process of bringing a law suit can be challenging, and in some cases devastating to personal reputations, careers, and finances, the False Claims Act provides that, although the full recovery of money goes to the federal government, the Government may then provide the relator with some portion of that recovery. You are not to allow the possibility of a relator's share to enter into your deliberations about the extent of the damages to which the United States is entitled.]

**Plaintiffs' Source(s):** 31 U.S.C. § 3730(d); *U.S. ex rel Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1036 (6th Cir. 1994).